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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/552,752

10/11/2005

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EXAMINER

WHITE, DENNIS MICHAEL

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

03/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,752	KRETSCHMANN ET AL.	
	Examiner	Art Unit	
	DENNIS M. WHITE	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 October 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/11/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Preliminary amendment filed 10/11/2005 is noted. Claims 1-24 are cancelled and claims 25-47 are new. Currently claims 25-47 are pending.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the serial number comprises a bar code must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 39 recites the limitation, "a film suitable not adapted for re-closing the opening." It is unclear as to the metes and bounds of the claims. Is the applicant claiming some property of the film (i.e. it does not work after the first use and is thus not adapted for re-closing)? or is the applicant claiming that the film does not cover the opening, thus being adapted for closing the opening? The applicants show a film 16 in Fig. 15 that is not covering the opening. For the prosecution of claim 39, the office is reading the limitation as a film that does not cover the opening and is thus not adapted to re-close the opening.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 25-39, 42-44, and 46-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Imburgia (USP 5,750,184).

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7. Regarding claim 25, 35, Imburgia teaches a biological indicators for monitoring a sterilization cycle ("sterilization testing apparatus") comprising a biological indicator 10 ("housing") including a pathway 30 ("channel") comprising a passageway 38 ("testing chamber"), a tortuous path 36 ("supply line for supplying a sterilizing medium to the testing chamber") (Fig. 2, col. 6 lines 37-47), an indicator to produce a color change of the growth medium ("at least one indicator located in at least the testing chamber for indicating completion of sterilization") (col. 10 lines 14-24) that can be seen because the first member 16 and second member 18 ("the housing being comprised of an assembly of at least two superimposed parts") are clear ("at least one of the housing parts comprises a transparent material which makes the indicator visible without opening the housing"), the tortuous path 36 ("supply line") being comprised of a pathway ("channel") formed by the first and second members 16, 18 such as where the first member 16 has a channel 36a formed in a serpentine shape ("in at least one of the housing parts") (col. 6 lines 19-24), the pathway ("channel") having an opening at one end thereof communicating with the testing chamber and an opening 32 at the other end thereof for communicating with a source of the sterilizing medium outside the housing (Fig. 2).

Regarding claim 26, 34, Imburgia teaches the channel 36a is formed in first member 16 (Fig. 2) ("supply line"). The channel is defined by the sides ("ridges") of the first member 16. ("at least one ridge formed on interior surfaces of at least one of the housing parts and side walls of at least one of the housing parts" ("at least one ridge is formed on only one of the housing parts").

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Regarding claim 27, Imburgia teaches a tortuous path with a length. It is noted that no length is specified, therefore the “length of the supply line relative to cross-section thereof is sufficiently great to prevent complete deaeration of the supply line during sterilization” is sufficiently broad to read on any length of the channel.

Regarding claim 28, Imburgia teaches the indicator is in the growth medium which is present in the pathway 30 (“a single indicator which extends over the entire length of the supply channel”) (col. 10 lines 14-24).

Regarding claim 29 Imburgia teaches the indicator in the growth media and another indicator 44 distributed over the entire channel 30 (Fig. 2: 44 and 30) (“a plurality of the indicators and distributed over the entire length of the supply channel”).

Regarding claims 30, 33, Imburgia teaches the device is sealed by RF sealing (“apart from said opening communicating with a source of the sterilization medium, the housing is hermetically sealed” “housing parts are fixedly secured together”) (Abstract, col. 9 lines 41-46).

Regarding claim 31, Imburgia teaches the pathway (“supply channel”) has parallel side edges (Fig. 2: 36) and is shown to have a uniform depth (“of square or rectangular cross-section”) (Fig. 3: 36a).

Regarding claim 32, Imburgia teaches the pathway 30 comprises a tortuous path 36 (“the supply channel follows a spiral or meandering path”) (Fig. 2).

Regarding claim 36, Imburgia teaches a perforations 150, 160, and 170 in the device 100 (Fig. 7) (“a breaking line along which the housing parts are manually breakable”). The perforations would provide access to the indicator in the pathway 30.

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Regarding claim 37, Imburgia teaches an adhesive strip 42 (“at least one tear strip in the housing parts”) (col. 8 lines 59-66). The tearing away of the adhesive strip (“tear strip”) provides access to the indicator.

Regarding claim 38, Imburgia teaches opening 32 in one of the housing parts for providing access to the indicator and a flap 48 to retard fluid communication beyond the fold line (“openable closure for the opening”) (col. 8 lines 64-68).

Regarding claim 39, Imburgia teaches the flap (“closure”) comprises an adhesive strip (“a film suitable”) that does not cover the opening (“not adapted for re-closing the opening” see 112 rejection above).

Regarding claim 42, Imurgia teach a chemical indicator 44 that is useful to indicate when the biological indicator 10 has been exposed to sterilizing conditions. (“scale” is sufficiently broad to read on any standard of measurement) applied by label 40 to member 18 (“applied to at least one of the housing parts”) (col. 7 lines 30-32)

Regarding claim 43, Imburgia teach the device 10 (“housing”) is comprised of label 40, first and second member 16 and 18, (“an assembly of at least three superposed parts”) and the pathway 30 (“channel”) is comprised of tortuous path 36 and pathway 38 (“at least two superposed sets of channels communicating with each other”)

Regarding claim 44, Imburgia teach a user can separate one or more individual units of the assemblage 100 before use by the perforations 170 (“housing parts are detachable from each other”) (col. and the second member 18 is then placed into contact with (for example, is lowered onto) first member 16 and adhered thereto, by conventional techniques, such as heat sealing or adhesive bonding. Examples of heat

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sealing include sealing through use of heated rollers, sealing through use of heated bars, radio frequency sealing, and ultrasonic sealing ("further comprising a seal between the housing parts") (col.5 line60-col. 6 line 3).

Regarding claim 46, Imurgia teach the device is made of plastic. Since the device is used for dry heat, steam, and ethylene oxide the plastic would be resistant to the heat used in the sterilization techniques. Furthermore since no particular temperature is specified "heat-resistant" is sufficiently broad to read on any plastic that is resistant to any amount of heat.

Regarding claim 47, Imurgia teach the device is made by the method for molding the first member to create cavities 20, 22 is through the use of a thermoforming process where materials are heated and then drawn or pushed into an appropriately shaped die using a vacuum or over-pressure. On contacting the die, the material cools and retains its new shape. ("the housing parts comprise at least one injection molded heat-resistant plastic") (col. 5 lines 40-46).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Imburgia (USP 5,750,184) in view of Kirckof (USP 6,488,890 B1).

Imburgia teaches the limitations of claim 25 as per above.

Regarding claims 40-41, Imburgia teaches a sterilization monitoring device comprising a label 40 with chemical indicator 44 indicates when the device has been exposed to sterilization conditions. Imburgia is silent that the device comprises a serial number applied to at least one of the housing parts and wherein the serial number comprises a bar code.

Kirckof teaches a sterilization indicator having sterilizing agent sensitive means in at least a portion of a readable code to provide: (i) a first indication to the code reader prior to the sterilization indicator being exposed to a sterilization process, and (ii) a

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second indication to the code reader after the sterilization indicator is exposed to at least a portion of the sterilization process. Preferably, the code is a bar code. The sterilization indicator 2 could include a bar code 17 printed from a colorfast, permanent ink that can be used for inventory purposes. The indicator 2 may also include other indicia 1 (Fig. 33, col. 8 lines 17-26). It is desirable to provide other indicia ("serial number") for inventory purposes in order to keep track of the sterilizing indicator devices.

Combining prior art elements according to known methods to yield predictable results is known. Therefore it would have been obvious to one of ordinary skill in the art, motivated by Kirckof, to provide the device of Imburgia with a serial number comprising a bar code in order to track the device for inventory purposes.

12. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Imburgia (USP 5,750,184) in view of Browne (WO 01/56618 A1).

Imburgia teaches the limitations of claim 25 as per above.

Regarding claim 45. Imburgia teach the sealing of the first and second member can be heat sealing or adhesive sealing. Imburgia is silent about the seal comprises a mat.

Browne teaches a re-usable sterilization device comprising at least two parts which are releasably connected together. Browne teaches the separable components having grooves brought together during the connection of the components to define respective channels with the intermediate compressible member ("seal comprising a

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mat") allows for easy cleaning and airing of the grooved means. Hence, the device according to the invention can be both readily aired and cleaned while nevertheless being re-usable. (Pg. 11 lines 1-7). It is desirable to provide an intermediate compressible member for sealing in order to have a re-usable sterilization device.

Simple substitution of one known element for another to obtain predictable results is held to be obvious. Therefore, it would have been obvious to one of ordinary skill in the art, as motivated by Browne, to substitute the adhesive seal of Imburgia with the intermediate compressible member of Browne because they are known sealing members to seal the device components together with the added advantage of allowing for the cleaning and airing of the device so it can be reused.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS M. WHITE whose telephone number is (571)270-3747. The examiner can normally be reached on Monday-Thursday, EST 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lyle A Alexander/
Primary Examiner, Art Unit 1797
/dmw/